

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

DIRECT MARKETING CONCEPTS, INC., et
al,

Defendants

CIVIL ACTION NO. 04-CV 11136GAO

Declaration of Dr. Leslie Axelrod.

I, Leslie Axelrod under oath declare as follows:

1. I am a Professor of Clinical Sciences at Southwest College of Naturopathic Medicine and have been full time faculty for the past ten years. In 1980, I received my Bachelor of Science, Magna Cum Laude in Human Nutrition from the University of Massachusetts. In 1987, I graduated from Bastyr University with a Doctorate of Naturopathic Medicine.
2. I am also a nationally certified and state licensed acupuncturist. In addition I completed a post doctorate program at the New England School of Homeopathy.
3. For the past five years I have been on staff at the county healthcare system, Maricopa County Integrative Health System. Attached is a true and accurate copy of my curriculum vitae. (Exhibit 1)

4. I have been in private practice for eighteen years, the last five in an integrative rheumatology practice with board certified rheumatologists.

5. I regularly prescribe MSM for arthritic conditions alone or in combination with other supplements such as glucosamine sulfate, chondroitin sulfate and botanicals.

6. I have found it to be very safe and effective in reducing pain and inflammation. Recently, I coauthored a research study at the college, "A Randomized, double blind, placebo-controlled clinical trial of methylsulfonylmethane for knee osteoarthritis pain" which was recently submitted for publication in a peer reviewed rheumatology journal.¹

7. Methylsulfonylmethane (MSM), also known as dimethyl sulfone, is a naturally occurring organosulfur compound and nutritional component of foods. Phytoplankton and algae decay produces sulfur compounds which when released into the atmosphere, react with ozone and ultraviolet light to produce MSM.

¹ Kim, L, Axelrod, LJ, Howard, P, et al., A Randomized, double blind, placebo-controlled clinical trial of methylsulfonylmethane for knee osteoarthritis pain, J Am Coll Nutr 2005;25:5:433 Abstract 78

8. MSM has also been found in a variety of foods including cows' milk (3.3 ppm), coffee (1.6 ppm), swiss chard (0.5 to 0.18 ppm) and beer (0.14 ppm).^{2 34} It is found in human urine, normally excreted at approximately 4-11 mg/day.⁵

9. The MSM that is used by the supplement industry is produced in the laboratory by reacting DMSO with hydrogen peroxide. The end product is water and MSM. The manufacturing process may vary depending on the manufacturer.

10. There are two different processes used, crystallization and distillation. Crystallization uses a wash and centrifuge process to purify, while the distillation process uses heat at a very high boiling point. The purity of MSM is more dependent on the quality of the raw materials in the crystallization process as compare to distillation.⁶

11. Quality of raw materials is very important since a large percentage of MSM is imported from China and India. These countries typically have lower water and manufacturing standards, along with a history of heavy metals and chemical contamination of its materials. Manufactured product may also vary in

² J Williams KIH, Burstein SH, Layne DS. Dimethyl sulfone:isolation from cows' milk. Proc Soc Esp Biol Med 1986;122:865-6

³ Steely, JS Chemiluminescence detection of sulfur compounds in cooked milk. ISulphur Compounds in Foods. American Chemical society.1994

⁴ Jacob, SW, Appleton, J, MSM The Definitive Guide, Freedom Press, 2003 ISBN 1-893910-21-0

⁵ Williams, KL, Burstein, SH, Layne DS, Dimethyl sulfone: isolation from human urine. Arch Biochem Biophys 1988;113:251-252

⁶ Jacob, SW, Appleton, J, MSM The Definitive Guide, Freedom Press, 2003 ISBN 1-893910-21-0

the percent of purity. The quality, process, and purity of MSM vary to such a degree as to make them dissimilar.

12. A review of certificates of analysis of different MSM products revealed that there are inconsistencies in purity. Three different manufacturers and suppliers showed a difference in purity on their certificates of analysis, i.e. 99.0%, 99.5% and 99.8% purity.^{7 8 9} This difference allows for a much higher amount of contamination, especially when heavy metals are measured in ppm. There is also a difference between MSM prescribed for veterinarian use or human use. The veterinarian version tends to be less pure.

13. MSM has been considered one of the least toxic biological substances. Rat studies on MSM indicate that it is a very safe supplement, even when given in very high doses. One toxicity study of rats found the acute oral median lethal dose (LD50) greater or equal to 17g/kg body weight for a form of 25.0% aqueous solution.¹⁰ Another rat study showed that no mortality, adverse effects or clinical signs of toxicity occurred with a single oral dose of 2 g/kg of MSM. In rats given a daily dose of 1.5 g MSM/kg body weight (equivalent to approximately 100 mg/day

⁷ Material Safety Data Sheet HH-PURE MSM, REFERENCE #: 3001033

⁸ SGS Group, guarantee of purity <http://www.oralchelation.com/methyl/technical/lab>.

⁹ NNFA GMP Certificate of Analysis, Cardinal Nutrition 2002

¹⁰ Acute Oral Toxicity of Sample No. 751, Dimethyl Sulfone 1 BT No. A6409, Sept 19, 1988 completed by Industrio Bio-Test Lab, In, Northbrook Illinois, unpublished

in humans) for 90 days had no adverse events in toxicology, gross pathology, hematology or histology.¹¹

14. In a study by Kim et. al. patients received six grams daily, the maximum recommended daily dose, for almost twelve weeks. No adverse events were seen. The patients were evaluated for neurotoxicity, cognitive function, bleeding disorders, gastrointestinal events and laboratory abnormalities. (CBC, Chem, lipid, UA and stool occult blood, homocysteine) There was no statistically significant change in incidence of adverse events. Laboratory findings did not significantly change either, except for a reduction in homocysteine, a positive finding.¹

15. MSM has been used for a variety of conditions alone or in combination with other supplements. Some reported uses that have been validated in the research include: arthritis pain, interstitial cystitis, chemoprotection and seasonal allergic rhinitis.^{12 13 14 15}

¹¹ Horvath K, Noker PE, Somfal-Relle S. et. al. Toxicity of methylsulfonylmethane in rats. Food Chem Toxicology 2002;40(10):1459-62

¹² Usha P, Naidu M. Randomized double-blind parallel, placebo-controlled study of oral glucosamine, methylsulfonylmethane and their combination osteoarthritis. Clin Drug Invest 2004;24:353-63

¹³ Childs, S, Dimethyl sulfone in the treatment for interstitial cystitis, Urol Clin Am. Feb 1994;21(1):85-88

¹⁴ O'Dwyer P, McCabe D, Dischl-Santanello Be, e. al. Use of polar solvents in chemoprevention of dimethylbenzanthracene-induced colon cancer. Cancer 1988;62:944-948

¹⁵ Barrager E, Veltman, J, et. al. A Multicentered, open-label trial on the safety and efficacy of methylsulfonylmethane in the treatment of seasonal allergic rhinitis, J Alt Compl Med 2002;8:2:167-173

16. Studies have shown an anti-inflammatory effect via inhibition of prostaglandin synthesis. It also has been shown to have an anti-oxidant effect by scavenging free radicals.¹⁶

17. Usha performed a twelve week study of 118 patients with mild to moderate osteoarthritis using a combination of either Glucosamine, MSM Glucosamine and MSM or placebo three times daily. The combination of MSM and Glucosamine significantly improved osteoarthritis symptoms, swelling and improved functional ability compared to placebo. The treatments were well tolerated.¹⁷ The study by Kim et. al. found MSM alone to be effective for the treatment of osteoarthritis pain of the knee.¹

18. Human studies have revealed that it is very safe when used at levels of six grams or less. Rat studies do indicate that it may be safer at higher levels. The limitation of the research is that most studies were performed for a maximum of ninety days or less.

19. In conclusion, methylsulfonylmethane is a naturally occurring substance with a very low toxicity. It is important to know the source of the product and to be able to trust that it is not contaminated with heavy metals or toxic compounds

¹⁶ Alam SS, Layman DL, Dimethyl sulfoxide inhibition of prostacyclin production in cultured aortic endothelial cells. Ann NY Acad Sci 1983;411:318-20

¹⁷ Usha P. Naidu M. Randomized double-blind parallel, placebo-controlled study of oral glucosamine, methylsulfonylmethane and their combination osteoarthritis. Clin Drug Invest 2004;24:353-63

The forms of MSM are notably different according to manufacturing process, source, quality, and purity.

I hereby declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Signed: Leslie Aphrodite M. K. Date: 10/11/05

Leslie Axelrod, NMD, L.Ac.

4628 E. Calle Redonda
Phoenix, AZ 85018
(602) 852-0985

HIGHLIGHTS OF QUALIFICATIONS

Eighteen years experience as a Naturopathic Physician
Professor at Southwest College of Naturopathic Medicine
State Licensed and Nationally Certified Acupuncturist
Areas of expertise include Rheumatology, Family Medicine, Gynecology,
Botanical medicine, Acupuncture and Oriental Medicine, Nutrition, Homeopathy,
and Cranial Sacral Therapy.

EDUCATIONAL DEGREES

Doctorate of Naturopathic Medicine - **Bastyr University**, Seattle, WA 1987

Acupuncture Degree - **Southwest College of Naturopathic Medicine and Health Sciences**, Tempe, AZ 1999

Acupuncture courses toward degree -**Northwest Institute of Acupuncture and Oriental Medicine** 1983-1987

Bachelor of Science Magna Cum Laude - Human Nutrition - **University of Massachusetts**, Amherst, MA 1981

PROFESSIONAL EXPERIENCE

Southwest College of Naturopathic Medicine Tempe, AZ
Southwest Naturopathic Medical Center, Scottsdale, AZ
1995-present (I took leave 1998-1999 to join an integrative medical practice)
Professor

Supervise Naturopathic medical students in clinical training and lecture in didactic courses

Maricopa Integrated Health System – Phoenix, AZ
Allied Health Professional Staff Member, Department of Family and Community Medicine

Naturopathic Physician and Acupuncturist, 1999-present
Staff member of Maricopa integrative Health System. Requested to be part of a health team incorporating alternative medicine into the county health system.
Established an extended site for Naturopathic students.

*Educational
Degrees*

*Professional
Experience*

Leslie Axelrod, NMD, L.Ac.

Arthritis Health, Scottsdale, AZ 2000 to present
Naturopathic Physician and Acupuncturist
Practice with two Rheumatologists in an integrative medical setting.

Banner Health System, Phoenix, AZ 1999
Naturopathic Physician and Acupuncturist
Joined with Howard Silverman, MD to create an alternative medicine option for patients and Naturopathic medical students

Arizona Centers for Health and Medicine, Scottsdale, AZ 1998-1999
Naturopathic Physician
Practiced medicine in an integrative medical setting, working closely with M.D.s, M.D(H) s, D.O's, an Acupuncturist, and MSW.

Oasis Naturopathic Medical Clinic, Prescott Valley, AZ 1987-1995
Naturopathic Physician
Established and maintained a private medical practice.

Williamstown Elementary School, Williamstown, MA 1980-1981
Nutrition Consultant
Incorporated nutrition into an elementary school program.

Women and Children First, Northampton, MA 1980-1981
Nutrition Consultant
Instructed recovering alcoholic women and children in nutrition

Lifeways, Northampton, MA 1981
Health Educator
Taught seminars for stress reduction to corporate employees

LICENSES HELD

Doctor of Naturopathic Medicine, Arizona, 1987 to present

Licensed Acupuncturist, Arizona, 2000 to present

National Certification in Acupuncture, NCCA, Diplomate of Acupuncture
1999 to present

Midwifery License – Texas 1988

Massage Therapist License – Washington 1986

*Licenses
Held*

Leslie Axelrod, NMD, L.Ac.

ADVANCED TRAINING AND CERTIFICATIONS*

Gynecologic Procedures for the Office, National Procedures Institute, Las Vegas Oct 2003.

Pharmacology Intensive, AzNMA, Phoenix 2003

Mental Illness and Acupuncture, Pacific College Symposium, San Diego 2002

Pharmacology Intensive, AzNMA, Phoenix 2002

Orthopedic Acupuncture and Tuina, Phoenix 2002

Pain Management (Beginning, Strategies and Advanced courses) with Tan Balance Method, San Diego, 1999, 2000, and 2001

Cellular and Intracellular Detoxification, Dickson Thom, ND 2000, 2001

Neurofascial Release – Stephen Davidson, DO 1999

Gynecology, Colposcopy / Biopsy training, MD Anderson Cancer Center, Houston, TX 1997

Sanum Therapies, Multiple seminars from 1988 to present

Intravenous Nutritional Therapy, Alan Gaby, MD, Phoenix 1997

Neural Therapy, Dietrich Klinghardt, Santa Fe, NM

Cranial Sacral Therapy, Upledger Institute, Level I and II, AZ 1991, 1996

Homeopathy Postgraduate training- New England School of Homeopathy 1992

Midwifery Internship, Casa de Nacimiento, El Paso, TX 1988

**The above listed seminars include only educational experiences with intensive training in a particular modality, therapy or technique. Seminars attended with multiple topics or disciplines (i.e. AANP, AzNMA Conference, Pacific Symposium on Acupuncture, AZ Family Planning Conferences, etc.) are not listed*

COURSES TAUGHT

Rheumatology – CLSC 861 This course discusses diagnosis and treatment of rheumatological issues.

Special Topics in Nutrition (current)– Nutr 830. Students are exposed to current research and nutritional therapeutics related to certain pathological conditions.

Advanced
Training

Courses
Taught

Leslie Axelrod, NMD, L.Ac.

Eyes, Ears, Nose and Throat (current)– CLSC 762. This course discusses diagnosis and treatment of common EENT conditions.

Case Management – CMGT 860. Lectured and coordinated speakers on clinical science cases.

Case Management – CMGT 880. Continuation of CMGT 860

Case Management – CMGT 784. Coordination of speakers for obstetric, gynecologic and urologic disorders.

GUEST LECTURES

Osteoporosis
Gynecology and Chinese Medicine
Gynecology and Puberty
Gynecology and Pelvic pain
Rheumatology case management
Gynecology case management
Pharmacology and Natural Hormones
Student Orientations – Case presentations
Clinical Diagnosis for EENT

CURRENT RESEARCH AND SCHOLARLY ACTIVITY

Kim, L, Axelrod, LJ, Howard, P, et. al., A Randomized, double blind, placebo-controlled clinical trial of methylsulfonylmethane for knee osteoarthritis pain, J Am Coll Nutr 2005;25:5:433 Abstract 78

Axelrod, LJ, Treating Autoimmune Disease Using Naturopathic Principles, Naturopathic Doctor News and Review, September 2005

MSM and Arthritis, Investigator – This double blind placebo controlled study is to investigate the effectiveness of MSM on fifty osteoarthritis patients. Accepted for publication in peer reviewed journal. .

NPBOMEX Board Examination Review – Assisted in the review and editing process of Board exam questions. July 2003

NPBOMEX Board Examination Questions - Developed questions in the areas of rheumatology, neurology, pediatrics, geriatrics and EENT for a state board exam. June 2003

COMMITTEE WORK

Chair, Clinical Practice Committee – Representing the clinical faculty in making clinical decisions for the college medical center 2003-present

Guest
Lectures

Research
and Scholarly
Activity

Committee
Work

Leslie Axelrod, NMD, L.Ac.

Chair, Continuing Medical Education Committee - Evaluating continuing medical education courses and seminars and approving for Naturopathic CME 2004-May 2005

Faculty Representative for Clinic Steering Committee – Representing the faculty as part of a team to help direct the clinic in objectives and goals. Summer 2003-present

Search Committee for VP of Clinical affairs – Assisting in the recruitment and selection of a VP of clinical affairs. September 2003

Senate Faculty Secretary, Position elected for 2002/2003 and 2004/2005.

Peer Review – Part of a team to evaluate faculty performance. Summer 2003-present.

Clinic Handbook Committee – Assisting in the revision of the clinic handbook. 2001- present.

Promotions Committee – Assist in the promotion and evaluation of faculty 2001-present

Advanced Standing – Assisted in the evaluation of enrolled and prospective students in their clinical ability to determine advanced standing status.

Standards of Medical Care – Helped in the formation of standards for the clinical faculty to adhere to in administering appropriate medical care.

Chart Review – Part of a team to institute a chart review policy at the medical center that will be utilized by the clinical faculty

Residency Selection – Assisted in the interviewing and selection of new first and second year residents for years 2001 and 2002.

Academic/Clinic Credit Conversion – Assisted in the formation of policy regarding conversion of the clinic to a new grading system.

Faculty Academic Load – Chair of committee to investigate and form policy on the academic workload of this institution, and compare to other naturopathic colleges

PROFESSIONAL SPEAKING

American Association of Naturopathic Physicians, Research track, Presented paper on MSM and OA of the knee, Phoenix AZ August 2005

University of Arizona Medical School, Acupuncture, Phoenix, AZ 2003

Banner Health System, Osteoarthritis Integrative Medicine, Phoenix, AZ 2002

Leslie Axelrod, NMD, L.Ac.

University of Arizona Medical School, Nutrition Research, Phoenix, AZ 2001

Classical Homeopathy, 5th Annual NCH Southwest Regional Conference, Tempe, AZ, Balancing the Cycles of Change 2000

Maricopa Integrated Health System to Maricopa County Hospital Staff, Complimentary Medicine and Pain Management, Phoenix, AZ 1999

Naturopathic Family Practice Board Certification -Instructor for Board Certification in Family Practice and Gynecology for Naturopathic Physicians, Phoenix, AZ 1997

PUBLIC SPEAKING AND COMMUNITY SUPPORT

Rheumatoid Arthritis Support Group, RA and Nutrition, Phoenix 2002

Sjogrens Support Group, Sjogrens disease and Naturopathic Medicine, Phoenix, 2001

John C. Lincoln Hospital, Alternative Therapies and Arthritis, Phoenix 2000

Polycystic Ovarian Syndrome Association – Medical Professional Appreciation Award 2000

Natural Medicine and Menopause Co-speaker Burt Webb, MD, Scottsdale 2000

Chinese Medicine, Franciscan Renewal Center, Phoenix, 1999

Women's Center of Yavapai County, Board member, Assisted in creating a homeless shelter for women and children of domestic violence Prescott 1994

LAY PUBLICATION INTERVIEWS

Mitchell, Deb. **The Women Doctor's Guide to Health and Healing**. Oxmoor House. To be published April 2003

Should You Believe the Headlines about Vitamins, Natural Health Magazine, Dec. 2001

Considering the Alternatives, Arizona Republic, Feb. 28, 2001.

Loeche, Barbara and Sara O'Donnell. **New Choices in Natural Healing for Women**, Rodale Press, Emmaus, PA 1997

*Professional
Speaking*

*Public
Speaking*

*Lay
Publication
Interviews*

Leslie Axelrod, NMD, L.Ac.

|